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May 26, 2020

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, NJ 08101

Honorable Joel Schneider, U.S.M.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, NJ 08101

Re: IN RE: VALSARTAN, LOSARTAN, & IRBESARTAN PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Kugler and Judge Schneider:

This letter is submitted on behalf of the Plaintiffs to address the agenda items for the May 27, 2020 case management conference.

1. Aurobindo/Hetero Production Deadlines

As per the Court's order, the Plaintiffs met and conferred with Counsel for Aurobindo Pharma Ltd. ("APL") and Hetero Labs Limited ("HLL") on 1) the start date of the "relevant period" for discovery, and 2) a date certain by which APL and HLL will complete their core discovery productions.

Start Date for the Relevant Period

The Parties agreed to the following start dates:

- Aurobindo Pharma Ltd. - January 1, 2012
- Hetero Labs Ltd. – January 1, 2011

Completion of Core Discovery

Hetero Labs Ltd. has agreed to produce core discovery pursuant to the following interim and final deadlines:

- On or by June 13, 2020, HLL will make a third production of core discovery, consisting of EIRs, 483s, and correspondence with the FDA;
- On or by July 13, 2020, HLL will make a fourth production of core discovery, consisting of any other outstanding core discovery items from 2013 onward not captured by the first three productions;
- On or by July 31, 2020, HLL will complete production of core discovery.

As to Aurobindo Pharma Ltd., Plaintiffs requested that APL, who has not yet produced any core discovery as to the Indian entity to date, complete production on or by June 26, 2020. APL requested a deadline of July 31, 2020 to complete core discovery. During a meet-and-confer, Plaintiffs requested certain interim dates between now and July 31, 2020, by which Aurobindo would commit to producing certain categories of core discovery (such as inspection reports, and correspondence with the FDA). Counsel for Aurobindo has not yet provided Plaintiffs with any dates certain for rolling core discovery productions between now and July 31, 2020. In the absence of these commitments to dates certain for interim productions, Plaintiffs cannot agree to July 31, 2020.

2. API and Manufacturing Defendants DFS's

Plaintiffs are not asking for information in the DFS that is duplicative of what Defendants are providing in the noncustodial productions. That is the forest. This is identification of the trees applicable to a particular plaintiff. Each request seeks to pinpoint the specific key facts which are important to the proof of each particular case. Defendants would cry foul if Plaintiffs suggested that a PFS was not necessary because all the information about a particular Plaintiff was contained in their produced medical records. Defendants should not be allowed to take a similar position with respect to the DFS, i.e., to throw millions of pages of information into the air and require each individual plaintiff to hunt for information specific to her case once the pages hit the ground. To the extent the Defendants are in possession of the information, and are certainly more familiar with the documents and where to locate specifics, it is a more efficient use of the parties time and resources for the Defendants to provide the requested information (or cite to specific documents where the information can be found). For example, during a recent meet and confer regarding the DFSs, Defendants suggested that some batch-specific information related to ZHP could be found in a specific document and then identified said document in a follow-up email at Plaintiffs' request:

> As for the spreadsheet I mentioned on our recent meet and confer, Plaintiffs can locate that document at PRINSTON000075648. This is an example of a document produced in core discovery that contains much of the batch-specific information that Plaintiffs currently seek through the DFS. Of course, as the Manufacturers have explained on multiple occasions, ZHP does not know whether valsartan API from a specific batch ended up in tablets dispensed to a particular plaintiff.

This email illustrates the efficiency and ease of requiring Defendants to provide (or identify) information specific to a particular plaintiff in the first instance, or at the very least – as a

compromise - to identify the foundational documents within which the category of information can be easily located.

A. Time to Complete the DFS

The Finished Dose Manufacturers would like 90 days to complete the DFS from the time that the Distributor, Repackager, Relabeler, and Wholesaler Defendants serve their DFS. The Distributors, Repackager, Relabeler, and Wholesaler Defendants also are seeking a 90-day response window. The APIs then propose to take yet another 90 days to complete their DFS after the Finished Dose Manufacturer serves its DFS. This timeline is simply unworkable. Taking these three 90-day segments together, assuming no group of defendants delays or serves its DFS late, these three documents will take ***nine months*** to complete. The information contained in these Defendant Fact Sheets is critical to understanding key aspects of each individual case, and will inform both parties' decisions when it comes to the Bellwether process. In order to keep this litigation on track, Plaintiffs suggest a 30-day timeline but have offered to compromise at 45 days for each DFS, subject to the Court's preference. This will allow the process to proceed on a more reasonable schedule.

B. Testing on any nitrosamine testing on the Affected API

Defendants indicated in an email to the PEC that, "[o]f course, as the Manufacturers have explained on multiple occasions, ZHP does not know whether valsartan API from a specific batch ended up in tablets dispensed to a particular plaintiff." This seems impossible, particularly since the Manufacturer Defendants have structured the DFS process in such a way that they receive specific NDC, batch, and lot information from pharmacies, and then the manufacturing defendants

provide further sales and distribution data to the API defendants prior to having to answer this question. To the extent that a manufacturer or API Defendant truly cannot tell a specific individual Plaintiff if she or he received pills containing NDMA, the manufacturer should still be required to answer in a formal discovery pleading that this is the case—there is simply no burden in requiring these Defendants to make such an admission. On the other hand, to the extent such information is available, the individual Plaintiff is entitled to this information on an individual basis, as it helps to demonstrate specific causation for that plaintiff. Defendants have indicated on multiple occasions that they plan to defend specific cause at trial, and allowing them to keep this relevant information secret squarely contradicts Rule 26, which allows for the discovery of "nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1).

C. Use of Solvents and Relevant Tests

Defendants have refused to provide information regarding solvents used to manufacture the API in the pills consumed by the individual plaintiffs. During meet and confer calls, Plaintiffs offered to narrow the list of solvents and certain tests performed on each lot and/or batch of API and finished dose drugs such that only solvents which either contained nitrosamines or that were capable of forming nitrosamines during the manufacturing process of the drugs taken by an individual plaintiff were subjects of the request. Plaintiffs further offered to narrow the list of solvents to those most material to the case, but Defendants failed to provide information on which those would be and simply eliminated the question. Plaintiffs request that the Defendants be required to produce information specific to an individual Plaintiff about the use of any solvent (fresh or recycled/recovered) which has the capacity to create nitrosamines during the

manufacturing process for the drugs taken by that plaintiff. This issue is central to the case as the solvents used in the manufacturing processes appear to be at the heart of the cause of the nitrosamine contamination. Similarly, Plaintiffs request that Defendants be required to produce any test results which could or do show the presence of nitrosamines pertaining to the specific medications taken by the plaintiff in question.

D. Recall Notices to Other Defendants

Defendants have also refused to produce the dates on which recall notices associated with contaminated pills ingested by an individual Plaintiff were provided to Defendants further down the distribution chain. Those notices are important evidence, confirming the contamination on a case specific level. Moreover, to the extent there was a delay in sending this notice, that information is germane to an individual Plaintiff's claim. Moreover, these notices provide the date on which each defendant further down the distribution chain was put on notice that it needed to take appropriate actions concerning the presence of nitrosamines in the drugs in question. Notably, Plaintiffs are not asking Defendants to reproduce documents they have already produced but instead are only seeking the dates on which these notices were sent out, based on the assumption that the notices will all have been produced and can be easily identified in the production.

E. Communications with Plaintiffs

Defendants assert they are only required to produce communications with Plaintiffs if a particular plaintiff contacted that defendant first. It is baffling that Defendants might have information regarding a specific plaintiff and then would refuse to produce that information. Defendants are sophisticated drug companies with departments and protocols directed to

collecting and handling both incoming and outgoing communications with consumers and physicians, thus providing Defendants with discrete files to search in order to obtain this information. Plaintiffs raised this with Defendants during a recent meet and confer, but Defendants have flatly refused to comply with this routine request.

F. Defendants' Possession of Recalled or Contaminated Batches:

Defendants have also refused to provide information regarding whether any affected API or drugs traceable to a particular Plaintiff were returned to their possession. This information will guide the Parties' discovery activities, Bellwether case selection, as it informs each specific plaintiff whether any materials associated with the pills they ingested may or may not be available for testing, and will impact expert and trial strategy.

G. Case-Specific Defenses:

Just as Plaintiffs are required to provide information to Defendants regarding issues which may bear on specific causation, each individual Plaintiff is similarly entitled to discover what, if any, defenses the defendants will be asserting regarding causation. Defendants should therefore be ordered to respond to this question in the DFS. To the extent they have not formulated an opinion, there is no burden on the Defendants to say so.

H. Document Requests:

As a result of the meet and confer sessions, Plaintiffs narrowed their document requests down to four, which seek only the most basic information regarding communications with individual Plaintiffs and the health care providers they identified in their PFS. Nonetheless, Defendants have rejected the proposal and instead want the ability to retain documents directly

relating to individual plaintiffs and their physicians, which would routinely be disclosed in Rule 26(a) Initial Disclosures in any single event personal injury case. Finally, Defendants should further be ordered to produce pharmacy reimbursement requests pertaining to individual plaintiffs, as this information is germane to class issues and will be relevant during class certification.

3. Manufacturer Sale and Pricing Production Deficiencies

Varying deficiencies exist for the sales and pricing data produced by the Manufacturer Defendants on May 15, 2020. ZHP/Solco's and Mylan's productions are the most deficient. ZHP/Solco initially produced only static PDF files of a few large spreadsheets, rendering those files essentially useless.

ZHP/Solco. Though ZHP/Solco has since produced native Excel files (as other Manufacturer Defendants did the first time), several major substantive deficiencies still exist with ZHP/Solco's data production. ZHP, among other things, (i) failed to produce *any* transactional pricing data such as the gross and net amounts charged to or paid by customers, even though exemplar invoices (and common sense) clearly show it possesses such information (not to mention this data is specifically called for in the parties' agreed-upon, Court-ordered document requests), (ii) has not produced *any* sales data predating 2017 (and for 2017-2018 it merely produced a list of 17 customers), (iii) has not produced sufficient financial data to understand its costs and profits, and (iv) will not produce any data dictionaries or field/column explanations (as required by the agreed-upon ESI Protocol) so Plaintiffs can understand the value in each field or column. Similar deficiencies existing Solco's data production. Plaintiffs sent a detailed letter to ZHP/Solco detailing the many deficiencies, and the parties conferred on Friday, May 22. Plaintiffs believe

that ZHP/Solco should promptly agree, or be directed by the Court, to produce data of similar caliber to that produced by other Manufacturer Defendants, along with data dictionaries of column/field key explanations.

Mylan. Similar to ZHP and Solco, Mylan failed to produce (i) data dictionaries or field/column explanations, (ii) quantity, as well as gross and net price, data for Mylan's sales of valsartan API; and (iii) quantity, as well as gross and net price, data for Mylan's sales of finished dose valsartan to Mylan's customers. Plaintiffs have requested a meet-and-confer to discuss these issues with Mylan. Plaintiffs believe that Mylan should promptly agree, or be directed by the Court, to produce data of similar caliber to that produced by other Manufacturer Defendants, along with data dictionaries of column/field key explanations.

Remaining Manufacturer Defendants. While some issues exist with the remaining Manufacturer Defendants' data productions (Teva, Aurobindo entities, and Hetero entities), they are not as major or pervasive as the issues with the data produced by ZHP, Solco, and Mylan. Plaintiffs have communicated with all remaining Manufacturing Defendants and hope to hear back from each soon.

4. Retailer/Wholesaler Macro Issues and Discovery Production

At Defendants' request, an additional extension to brief Macro issues was granted with Defendants' brief to be filed on June 16 and Plaintiffs' reply brief on June 22, 2020. On May 11, 2020, Plaintiffs requested that Retailer and Wholesaler Defendants provide information as to the feasibility of beginning a rolling production of documents that Defendants previously agreed to produce (i.e. those not subject to the Macro issues before the Court).

Subsequently, Plaintiffs met and conferred with Retailer defendants to finalize the narrowed disputes before the Court. Based on the Parties' continued discussions, which should be completed during the week of May 25th, Plaintiffs will revise and serve the Requests for Production as to Retailers and Retailer Defendants will respond to this discovery on a rolling basis, with the remaining discovery subject to the Macro briefing to be responded to after and in line with the Court's ruling.

5. Prioritization of Manufacturer Productions

On May 5, 2020 the parties had a conference call to discuss prioritization of the manufacturer productions, in accordance with the Court's Order that prioritization of discovery should occur by May 15, 2020. Following that call, on May 7, 2020 Plaintiffs sent a letter documenting their prioritization requests to the manufacturer Defendants. (Exhibit A – hereto). These requests were submitted to the Court on May 12, 2020 as an exhibit to the submission in advance of the May 13, 2020 status conference. On May 21, 2020, Plaintiffs emailed the defense to confirm a basic point that was assumed, in order to ensure no miscommunication on a critical category of documents: "that we did not explicitly list all of the relevant testing included in the document requests (including for example all chromatograms performed in connection with the manufacturing of API, use or reuse of solvents, and manufacturing of finished dose) in our prioritization request, because we assumed that would definitely be included in the initial production anyway, based on the Court's definition of the production obligations. If we were incorrect in our assumption please amend our prioritization requests to include this email. We would appreciate your confirmation."

On May 22, 2020, defense counsel responded to Plaintiffs' prioritization requests. (Exhibit B – hereto). Defendants' letter set forth no commitment by any Defendant to prioritize anything. Instead, Defendants advised that due to variability in the circumstances from Defendant to Defendant, each would separately reach out to confer with Plaintiffs at such undefined point in time as they may figure out what they may be willing/able to prioritize. Defendants also took this opportunity to remind Plaintiffs that the Court did not require them to disclose what had been collected. This was apparently an exclamation point on their refusal during the May 7, 2020 meet and confer to respond to Plaintiffs' request to understand what documents were already going to be produced in the initial production on July 15, 2020 pursuant to the Court's Order, and if there were any categories that definitely could not be produced until later in the year, so that Plaintiffs could more efficiently prioritize. On Saturday May 23, 2020, an attorney for ZHP wrote to schedule a call on May 28 or 29, 2020, but did not indicate anything about what categories of documents ZHP intends to prioritize, and Plaintiffs have no confidence at this point that a substantive exchange of information can be expected.

Defendants' position (to this point) that they don't have to provide any advance information about their productions, including their ongoing refusal to confirm or deny their intention to prioritize anything for production, makes it impossible for Plaintiffs to anticipate and prepare to receive the productions. In addition, Plaintiffs are unable to seek the Court's intervention in advance, in the event Defendants do not intend to produce prioritized categories of documents, or categories of documents that the Court reasonably expects to be included in the initial production. Plaintiffs gave significant consideration to the prioritization requests, which are focused on certain

key issues in the litigation, and believe that the manufacturing Defendants should at this point be required to comply with those requests absent a specific compelling reason, in light of the lead time granted by the Court.

6. Plaintiffs' Leadership Structure

Plaintiffs have submitted a motion to supplement the Steering Committee with several law firms who have indicated an interest in developing the Losartan and Irbesartan aspects of the litigation. This motion [Dkt. No. 435] is set for June 15, 2020 to be heard on the papers. Plaintiffs intend to supplement this list by letter in order to request the addition of Daniel Levin of Levin, Sedran & Berman, to the Plaintiffs' Steering Committee. Mr. Levin has filed additional TPP claims that have been coordinated in this MDL and has asked to serve on the TPP committee.

7. Plaintiff Fact Sheets

Defendants have submitted a massively overbroad list of cases with purported PFS deficiencies. The first problem is procedural, as it is not represented that consultation with each firm has occurred in accordance with the Court's expectations, including after a law firm has addressed purported deficiencies, before coming to the Court to request first listing for potential entry of an order to show cause. The second issue is substantive, flowing from the defense's errors in describing compliant productions as deficient, and over-inclusive definition of a core deficiency that can trigger and order to show cause. For example, at Defendants' request, plaintiffs provided authorizations signed by the plaintiff, but not filled out beyond that – so the defense could fill in the doctor or other entity – yet the defense is claiming those authorizations to be deficient. Another example is the defense's claim that supplements to the PFS must all be signed by the plaintiff.

That has never been agreed to, was not the process followed in Benicar, and would create a tremendous unnecessary burden, for example requiring a plaintiff to sign off every time a new medical record is produced. Supplements are submitted by the plaintiff's law firm, and become a part of the PFS as a matter of course.

An example of a claimed deficiency that is clearly not core is the failure to provide medical expense amounts, which a plaintiff might not even have at the present. That is an example of a potential gap that would routinely be addressed in the course of discovery, and would never rise to the level of a core deficiency. Another example of a claimed deficiency that is clearly not core is a plaintiff responding that the plaintiff does not recall answers to certain questions. For example, a surviving spouse did not recall the treating physician's name for a gallbladder disease that is tangential to the core injury of her deceased spouse. A Plaintiff not recalling information, especially under such circumstances, should not rise to the level of a deficiency and is certainly not a core deficiency. Another example that the defendants repeatedly cite as a core deficiency in multiple listings is that plaintiffs failed to disclose the outcome for how their hypertension was treated. First, this wouldn't rise to the level of a core deficiency, and second, even the plaintiffs' multiple responses in both the PFS and their individual responses to the defendants' deficiency letters explain that the plaintiff is continuing to treat their hypertension.

Indeed as recently as yesterday (even after the parties had an extensive discussion about the high volume of inaccurately alleged "deficiencies"), plaintiffs continued to receive deficiency notices with many of the same errors. Indeed, in one notice, many questions were cited as "unanswered," when in fact, answers had been provided. In others, the PFS does not have a "N/A"

box to check, so the lack of an answer is the only option for a plaintiff if the question does not apply. This should not automatically be construed as a deficiency. For these reasons, Plaintiffs request that the proposed first listing of cases for an ultimate order to show cause should be denied so that the criteria and process can be clarified, to avoid unnecessary back and forth, and burden on the Court.

8. Short Form Complaints

On May 20, 2020, Defendants identified two categories of purported Short Form Complaint ("SFC") deficiencies. One is "improperly filed" SFCs. This list includes only one case which is properly filed, but the SFC information is not properly populating in Centrality. The parties have conferred and hope to address this issue informally. The other list identifies five cases (represented by three different firms) that purportedly "over-identify" defendants. Plaintiffs' leadership has liaised with these counsel and hope these issues will be addressed by the next CMC.

Thank you for your courtesies and consideration.

Respectfully,

ADAM M. SLATER